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developed in NSCLC, has been established here in SCLC. Patients on amrubicin experienced less symptom deterioration during treatment.

A228

### LESSONS LEARNED FROM HTA COST EFFECTIVENESS EVALUATIONS OF NEW CASTRATION-RESISTANT PROSTATE CANCER MEDICATIONS

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<sup>1</sup>Quintiles Global Consulting, Levallois-Perret, Ile-de-France, France, <sup>2</sup>Quintiles Global Consulting, Hoofddorp, The Netherlands, <sup>3</sup>Astellas Pharma Global Development, Leiderdorp, The Netherlands OBJECTIVES: Gain insights into Health Technology Assessment (HTA) agencies expectations regarding Health-Related Quality of Life (HRQoL) for cost-effectiveness evaluations of new medications for treating Castration-Resistant Prostate Cancer (CRPC). METHODS: In January 2012, 61 HTA agencies websites were scanned to identify HTAs of new medications for the treatment of CRPC published from 2005 to present. Only those evaluating the cost-effectiveness of new technologies were retained and analyzed for a better understanding of HTA agencies' expectations regarding HRQoL in CRPC. RESULTS: 39 HTAs were identified, 12 of which are currently in progress. The 27 published reports comprised 12 technology appraisals, 9 horizon scanning reports and 6 literature reviews. Only 9 of the 12 technology appraisals evaluated cost-effectiveness, these included seven appraisals on three drugs: IQWiG (Germany) assessed abiraterone; NICE (England & Wales) accepted docetaxel and rejected cabazitaxel; SMC (Scotland) rejected docetaxel and cabazitaxel; CVZ (Netherlands) accepted cabazitaxel; PBAC (Australia) accepted docetaxel after two rejections and rejected cabazitaxel. Uncertainty regarding HRQoL measures was the most often cited negative comment. For both docetaxel and cabazitaxel, the absence of quality of life measures from the main phase III trials and uncertainty around utility values were cited as reasons for rejection by NICE, SMC and PBAC. The CVZ accepted cabazitaxel for temporary reimbursement on the understanding that further subpopulation analysis and more data on utilities will be needed. The IQWiG assessment of abiraterone commented on uncertainties regarding the validity of the QoL questionnaire and restrictions in subgroup analyses. **CONCLUSIONS**: Our review indicates the need to include comprehensive quality of life measures in phase III trials for new drugs to treat CRPC, ensure these can be mapped into robust utility values and conduct meaningful CRPC subpopulation analyses. Further insights will be gained in the near future with the publication of CRPC HTAs currently in progress.

### PATIENT REPORTED OUTCOMES IN ONCOLOGY CLINICAL TRIALS: ARE YOU CAPTURING THE LINGUISTIC DIVERSITY OF THE PATIENT POPULATION IN INDIA?

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OBJECTIVES: Data collected using patient reported outcomes (PRO) tools in clinical trials provide unique information about patients' experience with their treatment. One of the major challenges with conducting clinical trials in linguistically diverse countries such as India, however, is identifying and using PRO scales that are linguistically validated in most of the representative regional languages. Lack of availability of linguistically validated scales can limit the participation of a relevant population from clinical trials. Therefore, the objective of this study was to determine if the PRO instruments used in clinical trials are linguistically validated in local languages across the various regions in India. For this study we limited our therapeutic area focus to clinical trials conducted in oncology. METHODS: A detailed review of the registered trials in clinicaltrials.gov was conducted using quality of life (QoL) and oncology as key words. Identified articles (n=103) were screened to exclude trials where OoI, was not measured and studies with n A 30. ProOoIJD and official websites of questionnaires were used to determine the availability of translations and linguistic validity of the questionnaires included in clinical trials. RESULTS: EQ-5D is the most commonly used generic instrument in oncology trials and is validated in most 11 Indian languages. EORTC-QLQC30, EORTC-QLQH&N35, EORTC-QLQBR23 and EORTC-QLQLC13 are the most commonly used cancer specific instruments and are validated in approximately 10 Indian languages. None of the generic or disease specific cancer instruments have been translated or linguistically validated for the Eastern & North-Eastern regions in India in languages such as Oriya, Santhali, Assamese, and Manipuri thereby limiting the participation of patients from these regions in clinical trials. CONCLUSIONS: The results of our analysis indicate that future efforts need to focus on translating and validating PRO instruments in 14 different Indian languages that should include the North Eastern regions of India

# CANCER - Health Care Use & Policy Studies

## **PCN114**

### USE OF ANTIDEPRESSANTS AMONG INDIVIDUALS WITH CANCER: A SYSTEMATIC REVIEW

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OBJECTIVES: Antidepressants (ADs) are primarily used to treat depression and anxiety among individuals with cancer and depression; however ADs are also being used for symptomatic relief from hot-flashes, neuropathic-pain, and fatigue in this population. Although there is a lack of robust evidence on the effectiveness of ADs in this population, and conflicting reports of a possible association between AD use and risk of recurrence of certain cancers exists; ADs are still being prescribed in this population. Thus, the objective of this study was to systematically review the extent of any AD use among individuals with cancer. METHODS: A systemic literature search was conducted using 4 electronic databases (PubMed, CINHAL, PsychINFO, and Web-of-Science), and cross-referencing. Studies starting from 1975 to 2011, and from all countries were assessed. Eligibility criteria used for the extraction of studies included: 1)full articles published in peer-reviewed journals in English-language only; 2) observational studies with data on any use or prescription of ADs; and 3) adults and children aged >1 year diagnosed with cancer (all types and stages of cancer were included). Studies on the use of psychotropic agents other than ADs or psychotherapy were excluded. After data extraction, number and percentages of individuals with cancer using ADs were calculated. RESULTS: The search yielded 1880 studies, 14 of which met the predefined inclusion criteria. Overall, the rates of AD use ranged from <1%-26% in varying subgroups of cancer patients; with lower rates in pediatric cancer patients (7%-12.3%), and in those with advanced-stage cancers (7.4%-16%). Rates also varied according to the type of cancers: breast (11.5%-34%), prostate (7%-18.8%), colon (7.5%-17.3%) and lung (7.2%-13.7%). The rates were higher among individuals with cancer and clinically diagnosed depression (12%-66.6%). CONCLUSIONS: Our descriptive results suggest that AD use may be associated with cancer site and stage, and presence of clinically diagnosed depression; and is lower in pediatric and advanced-stage cancer patients.

### PCN115

### PATTERNS OF CARE IN PATIENTS WITH MYELODYSPLASTIC SYNDROMES TREATED WITH HYPOMETHYLATING AGENTS

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OBJECTIVES: Hypomethylating agents (HMAs), decitabine and azacitidine, are indicated for use in treatment of myelodysplastic syndromes (MDS), however only a minority of patients receive HMAs. Our objective was to examine patterns of treatment associated with FDA-approved 5-day decitabine (DEC-5) and 7-day azacitidine (AZA-7) and off-label 5-day azacitidine (AZA-5) in MDS patients. METHODS: We identified MDS patients with an initial HMA treatment between July 1, 2005 to June 30, 2009 in 2 large insurance claims databases. Index date was the date of initial HMA treatment. Patients were stratified into: DEC-5, AZA-7, or AZA-5, based on their first cycle of treatment and were followed for 6 months. We described the number of unique cycles of index treatment and treatment gaps (days of missed treatment) in these groups. RESULTS: We identified 18,706 patients with MDS; 546 were treated with HMAs and were included in the study (156 received DEC-5, 176 received AZA-5 and 214 received AZA-7). Mean age was similar across groups: 68.8-71.2 years. Neutropenia was more common before treatment initiation in the DEC-5 (34.6%) group than in AZA-5 (22.7%) and AZA-7 (26.6%; p<.05) groups. There were 1,701 treatment cycles: 431 DEC-5 (per patient mean:2.8; median:2), 586 for AZA-5 (mean:3.3; median:3), and 684 for AZA-7 (mean:3.2; median:3) (p<0.05 for means). DEC-5 cycles had the fewest gaps: 94.9% had no treatment gaps, compared to 89.1% for AZA-5 and 23.4% for AZA-7. Among DEC-5 cycles, 3.2% had a 2 day gap, compared to 7.2% for AZA-5 and 66.5% for AZA-7 (p<0.001). CONCLUSIONS: In this retrospective claims analysis, few MDS patients were treated with HMAs. Among those who received HMAs, decitabine patients were more likely to have prior neutropenia. Between the 2 FDA-approved regimens, DEC-5 and AZA-7, there were significantly fewer gaps with decitabine treatment. More treatment gaps were observed with use of longer AZA regimen.

### USING THE MODIFIED RAND/UCLA DELPHI PROCESS TO PRODUCE TREATMENT CONSENSUS IN UNRESECTABLE MIDGUT GASTROINTESTINAL NEUROENDOCRINE TUMORS

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OBJECTIVES: Comprised of carcinoid and pancreatic neuroendocrine tumors (NETs), gastrointestinal NETs give rise to diverse clinical syndromes. Current treatment guidelines lack some specificity. We summarize an expert panel consensus on medical treatment of well-differentiated (grade 1-2) unresectable midgut NETs. METHODS: The modified RAND/UCLA Delphi process was used to collect NET treatment appropriateness ratings. The process involved recruitment of physician experts (e.g., by specialty, geography, practice), literature review, and collection of ratings before and after a face-to-face discussion. Experts and moderator were blinded to funding source. Patient scenarios were rated on a 1-9 scale on appropriateness of various therapies and were labeled as appropriate, inappropriate, or uncertain. Scenarios with >2 ratings in 1-3 and >2 in 7-9 range were considered to have disagreement. RESULTS: Panelists (age: 38-63 years) were from northeast, midwest, south, and west regions. Panelists had practiced for a mean 15.5 years and reported seeing 25 to 800 NET patients per year. Panelists rated 202 scenarios in midgut NETs. The proportion on which there was disagreement decreased from 11.7% (23 scenarios) before the meeting to 4.5% (9) after. After the meeting, 49% (99 scenarios) were rated inappropriate, 29.7% (60) were uncertain, and 16.8% (34) were appropriate. Resulting consensus statements include: 1) it is appropriate to use somatostatin analogs as 1st-line therapy in all patients; 2) it is appropriate to increase the dose/frequency of octreotide-LAR as  $2^{\mathrm{nd}}$ -line therapy in patients with uncontrolled symptoms up to 60 mg every 4 weeks or up to 40 mg every 3 or 4 weeks for refractory carcinoid syndrome; and 3) as 3<sup>rd</sup>-line therapy, antiangiogenic therapy may be active in patients with carcinoid tumors. CONCLUSIONS: Treatment consensus obtained in this study is concordant with NCCN recommendations. The Delphi process, however, permitted more detailed medical treatment guidelines in a range of key areas in midgut NETs.

### AN EXPERT PANEL CONSENSUS ON MEDICAL TREATMENT OF NON-MIDGUT UNRESECTABLE NEUROENDOCRINE TUMORS

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OBJECTIVES: Gastrointestinal neuroendocrine tumors (NETs) are rare and current treatment guidelines lack specificity in some clinical areas. We present a panel consensus on medical treatment of well-differentiated (grade 1-2 tumors) unresectable non-pancreatic non-midgut NETs. METHODS: NET treatment appropriateness ratings were collected using the RAND/UCLA Delphi process. We recruited physician experts (criteria: specialty, geography, practice), reviewed NET treatment literature, and collected 2 rounds of ratings (before and after a face-to-face meeting) from the experts. Experts and the moderator were blinded to the funding source. Patient scenarios (rated on a 1-9 scale indicating appropriateness of various interventions for a given scenario) were labeled as appropriate, inappropriate, or uncertain. Scenarios with >2 ratings from 1-3 and >2 from 7-9 range were considered to have disagreement and were not assigned an appropriateness rating. RESULTS: Ten panelists had a mean age of 50.4 years. Specialties represented were medical and surgical oncology, interventional radiology, and gastroenterology, and all practices were affiliated with academic institutions. Panelists had practiced between 6-33 years. Among 202 non-midgut rated scenarios, disagreement decreased from 16.2% (32 scenarios) before the meeting to 3% (6) after. In the  $2^{\rm nd}$ round, 42.1% (85 scenarios) were rated inappropriate, 34.2% (69) were uncertain, and 20.8% (42) were appropriate. Consensus statements from the scenarios include: 1) observation is appropriate in patients with no symptoms and low-volume radiographically-stable disease; 2) somatostatin analogs may be appropriate in patients with secretory symptoms; and 3) everolimus or interferon- $\alpha$  can be considered in patients who progressed radiographically or symptomatically on somatostatin analogs. CONCLUSIONS: We obtained appropriateness ratings of variety medical therapies in NETs from expert physicians. The Delphi process enabled participants to systematically quantify their assessment of the literature in a valid and reliable way while improving overall panel consensus on the appropriateness of medical therapies in non-midgut NETs.

# PCN118

### PROMOTING TOBACCO CESSATION AMONG CANCER PATIENTS: A NATIONAL SURVEY AMONG ONCOLOGY PROVIDERS IN THE UNTIED STATES

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OBJECTIVES: Tobacco use following cancer diagnosis is a serious concern for negative health outcomes. Despite ill-effects of tobacco among cancer patients and negative implications for treatment, many patients continue to use tobacco. On $cologists\ have\ a\ pivotal\ role\ in\ promoting\ to bacco\ cessation\ throughout\ treatment.$ This study assessed knowledge, readiness, and willingness to conduct and promote tobacco cessation counseling among a national sample of currently licensed practicing US Oncology providers. METHODS: A brief survey was administered in July 2011 via e-mail (N=3006) and US postal mail (N=1000). Samples were obtained from SK&A Information Services, Inc., which used verified addresses and broadcast e-mail surveys with one follow-up. Response rates were 0.6% for e-mail (N=19) and 9.6% for postal mail (N=96), with a 2.9% overall response rate (N=115). RESULTS: Results showed a majority of oncologists do the following often/almost always with patients: ask about tobacco use (96.6%); document tobacco use (93.1%); discuss tobacco use as a cancer risk factor (87.9%); counsel patients on quitting (72.8%); and assess readiness to quit (68.7%). Findings, however, also reported a majority of oncologists do the following never/rarely with patients: provide information about secondhand tobacco smoke (53.5%); provide information on quitlines (59.7%); provide brochures and self-help guides (64.3%); and follow the 5A's model for tobacco treatment (68.6%). On a scale of 0-10, providers indicated they were generally comfortable providing cessation counseling [mean=7.0; SD=2.4]; however, providers were less willing to participate in a tobacco cessation training program for assisting patients with quitting [mean=5.2; SD=3.4]. CONCLUSIONS: Findings suggest oncology providers are asking, documenting use, and counseling patients who continue to use tobacco during treatment. Education targeting providers can increase knowledge and practices related to the 5A's treatment model, promoting quitline and self-help information for patients. Effective strategies increasing provider willingness to attend tobacco treatment training sessions should also be encouraged.

### PCN119

### CHEMOTHERAPY TREATMENT AND SURVIVAL OUTCOME

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OBJECTIVES: The main objective was to determine the chemotherapy treatment and outcome. METHODS: Data was collected from 1 June 2008 till 31 December 2008 in Hospital Kuala Lumpur (HKL) using web-based application. Survival data would be obtained via linkage with Registration Department after four years. Data analvsis was with STATA statistical software, RESULTS: The total number of patients was 1192. There were 56% females and the most common age group was 50-59 years. The major ethnic groups were Malay (46.5%), Chinese (37.3%) and Indians ( 13.8%). Most patients at the oncology clinic at HKL have good performance status with ECOG 0-1 (61.5%). The most prevalent cancers were breast cancer (24.5%), colorectal cancer (17.4%), bronchus and lung cancer 8.6%, cervical cancer 6.5% and nasopharyngeal cancer (NPC) 6.2%. Most solid tumours were treated by multimodality. 48.8% received 2 or more modalities . There were 547 patients (45.9%) that received radiotherapy and 32.2% that received chemotherapy. 384 patients were given cytotoxic chemotherapy. Most patients (84,1%) received just one regime. The most common regime was a combination of Fluorouracil, Epirubicin and Cyclophosphamide ie FEC (16.4%.) The most often used cytotoxic drugs used were Fluorouracil (26.3%), Cisplatin (15%) followed by Cyclophosphamide (9.9%), Epirubcin (7.3%), Capecitabine (6.4%), Docetaxel (4.2%), Gemcitabine (3.7%). The most often used route of administration was intravenous (92.6%) mostly infusion as opposed to bolus. Capecitabine was the cytotoxic dug that was the most widely used in the oral form. CONCLUSIONS: This is only sub-study of a long term research that began in 2008 in HKL.. Patterns in chemotherapy usage would change as new drugs emerged in the Formulary. The database would be sustained as a platform for future researches and for survival analysis. (283 words).

### THE IMPACT OF UNIVERSAL HEALTH INSURANCE COVERAGE ON USE OF MEDICINES FOR NON-COMMUNICABLE DISEASES IN THAILAND

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OBJECTIVES: In 2001, Thailand implemented the 30 Baht Scheme, a public insurance scheme that covers the poor and uninsured and pays providers through a capitated payment scheme. Our objective is to evaluate the impact of the 30 Baht Scheme on use of medicines in Thailand for three non-communicable diseases: cancer, cardiovascular disease, and diabetes. METHODS: We used an interrupted time series design to measure the impact of the 30 Baht Scheme on total pharmaceutical market volume and market share. We used IMS Health data on quarterly purchases of medicines from hospital and retail pharmacies from 1998 to 2006. RESULTS: The 30 Baht Scheme was associated with long-term increases in hospital sector sales of medicines for conditions that can be adequately treated in outpatient and primary care settings (e.g., diabetes, high cholesterol and high blood pressure). The policy was associated with no change in sales of medicines for more life-threatening diseases, which are more appropriately treated in secondary or tertiary settings (e.g., myocardial infarction, stroke and cancer). The majority of sales were for essential medicines, yet there were also post-policy increases for non-essential medicines. Immediately following the reform, there was a significant shift in hospital sector market share by licensing status for most classes of medicines. We observed large increases in government-produced products, primarily at the expense of branded generics. **CONCLUSIONS:** Our results suggest that expanding health insurance coverage with a medicines benefit to the entire Thai population increased the volume of medicine sales in primary care hospitals. Our study, however, also suggests that implementation of the 30 Baht Scheme may have been associated with possibly undesirable effects: increased use of non-essential medicines and decreased use of less expensive generics and medicines in secondary and tertiary settings. Thorough evaluation of desired and undesired effects of universal health insurance programs are urgently needed.

## EVALUATION OF AROMATASE INHIBITOR UTILIZATION AND FAILURE IN POST-MENOPAUSAL WOMEN WITH ADVANCED ER+/HER2- BREAST CANCER

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**OBJECTIVES:** To compare the demographic, clinical and treatment characteristics

of post-menopausal women with advanced ER+/HER2- breast cancer (BC) treated with aromatase inhibitors (AI) who experienced 0 or  $\geq$  1 AI failure (AIF). **METHODS:** Women ≥ 55 years old, newly diagnosed with metastatic ER+/HER2- BC (index) were identified from the 2006-2010 Thomson Reuters MarketScan databases. Patients in the 6-month pre- or variable post-index periods treated with endocrine (ET: tamoxifen, fulvestrant) or AI (anastrozole, letrozole, or exemestane) therapy (ER+) and not with trastuzumab or lapatinib (HER2-), with no pre-index diagnosis of primary cancer other than BC, and post-index treatment with  $\geq$  1 AI were retained. AIF was defined post-index as a switch to an alternative AI, ET, or chemotherapy, or AI discontinuation with no further BC treatment. RESULTS: Among 4274 ER+/ HER2- BC patients studied, 61% had  $\geq$  1 AIF (80% had 1 and 20% had 2+ AIFs). There was no difference in pre-index AI use (54.4% no AIF, 51.8% AIF; p=0.093). At index, AIF patients were more likely to be Medicare-eligible (57% vs. 51%) with liver (7% vs. 4%), lung (10% vs. 8%), bone (56% vs. 48%), and brain (7% vs. 5%) metastases, all p<0.03. Mean follow-up days was shorter for AIF patients (486 vs. 522, p=0.006). First line AI and ET treatments were respectively 95% and 5% for AIF and 97% and 3% for no AIF patients. The most common first line therapy was an astrazole (49%